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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,657	08/25/2006	Jan Mollenhauer	4266-0132PUS1	1500

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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01/25/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/590,657	Applicant(s) MOLLENHAUER ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,35,37 and 40-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-60 and 64-66 is/are allowed.
- 6) ☒ Claim(s) 31,35,37 and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1October2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Office Action, received 1 October 2009, is acknowledged. Claims 32, 33, 34, 36, 38 and 39 have been cancelled. Claims 31, 35, 40, 45, 49, 52, 55, 58, 61, 63 and 64 have been amended.
2. Claims 31, 35, 37 and 40-66 are pending and under consideration.

Objections/Rejections Withdrawn or Moot

3. The objection to claim 33 because the bacterial names should be in italics, is moot in light of the cancellation of the claim.
4. The objection to claims 45, 52, and 58 because the bacterial names should be in italics, is withdrawn in light of the amendment of the claims.
5. The rejection of claim 62 under 35 U.S.C. 112, second paragraph, as being indefinite for "use" is withdrawn in light of the amendment of the claim.
6. The rejection of claims 32, 33, 34, 36, 38 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for "patient in which thereof", is moot in light of the cancellation of the claims.
7. The rejection of claims 31, 35 and 37 under 35 U.S.C. 112, second paragraph, as being indefinite for "patient in which thereof", is withdrawn in light of the amendments of the claims.
8. The rejection of claims 32, 33, 34, 36, 38 and 39 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment or prevention of all diseases caused by all agents, is moot in light of the cancellation of the claims.
9. The objection to Figures 1-11 because the labeling of the figures is handwritten, is withdrawn in light of the submitted replacement drawings.

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10. The rejection of claims 40-48 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of the claims.
11. The rejection of claims 49-54 under 35 U.S.C. 112, second paragraph, as being indefinite for "shortened" sequences, is withdrawn in light of the amendment of the claims.
12. The rejection of claims 55-60 under 35 U.S.C. 112, second paragraph, as being indefinite for "shortened" sequences, is withdrawn in light of the amendment of the claims.
13. The rejection of claims 64-66 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment or prevention of all diseases caused by an agent possessing ≥ 1 accessible sulphate and/or ≥ 1 accessible phosphate group by administration of a therapeutically effective amount of ≥ 1 amino acid motif comprising 11 contiguous amino acids derived from a polypeptide comprising SEQ ID NO:1 or of a nucleic acid encoding said amino acid motif, is withdrawn in light of the amendment of the claims to recite that the method is an *in vitro* method.

Rejections Maintained

14. The rejection of claims 31, 35 and 37 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment or prevention of all diseases caused by all agents, is maintained.

Applicants argue that the specification provides sufficient for methods for treating or preventing a disease caused by all non-living compounds which possess ≥ 1 accessible sulphate and/or ≥ 1 accessible phosphate group comprising administration of a therapeutically effective amount of a polypeptide or nucleic acid.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in the original rejection. While the specification does teach various binding assays, the only *in vivo* example utilizes BMBT1-knockout mice to show that these

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deficient mice are more sensitive dextrin sodium sulphate. The specification provides no examples of administration of DMBT1 providing treatment or prevention of disease.

15. The rejection of claims 61-63 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment or prevention of all diseases caused by an agent possessing ≥ 1 accessible sulphate and/or ≥ 1 accessible phosphate group by administration of a therapeutically effective amount of ≥ 1 amino acid motif comprising 11 contiguous amino acids derived from a polypeptide comprising SEQ ID NO:1 or of a nucleic acid encoding said amino acid motif, is maintained for reasons of record.

Applicants argue that the specification provides sufficient for methods for treating or preventing a disease caused by all non-living compounds which possess ≥ 1 accessible sulphate and/or ≥ 1 accessible phosphate group comprising administration of a therapeutically effective amount of a polypeptide or nucleic acid.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in the original rejection. While the specification does teach various binding assays, the only *in vivo* example utilizes BMBT1-knockout mice to show that these deficient mice are more sensitive dextrin sodium sulphate. The specification provides no examples of administration of DMBT1 providing treatment or prevention of disease.

Conclusion

16. Claims 31, 35, 37 and 61-63 are finally rejected.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 21, 2010